IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re patent application of

Irena Slage	Confirmation No. 9500
Serial No. 09/921,595	Group Art Unit 2157
Filed August 6, 2001	Examiner Salad

For SYSTEM AND METHOD FOR MANAGING, MANIPULATING, AND ANALYZING DATA AND DEVICES OF A DISTRIBUTED NETWORK

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

SUBMISSION OF APPELLANTS' BRIEF UNDER 37 C.F.R. §41.37

This brief is in furtherance of the Notice of Appeal filed in this case on June 28, 2007.

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This brief contains these items under the following headings, and in the order set forth below (37 C.F.R. §41.37(c)):

I. REAL PARTY IN INTEREST

The real party in interest in the appeal is:

☐ the party named in the caption of this brief.

☑ the following party: Firelogic, Inc., Washington, D.C. 20006

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals, interferences or judicial proceedings that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal:

☑ there are no related appeals, interferences or judicial proceedings related to, which directly affect or may be directly affected by or have a bearing on the Board's decision in this pending Appeal.

☐ these are as follows:

III. STATUS OF CLAIMS

The status of the claims in this application are as follows:

A. Total number of claims in Application

Claims in the application are: Claims 2 and 4-27, totaling twenty four (24) total claims.

B. Status of all the claims:

1. Claims cancelled: claims 1, 3, 28-39
2. Claims withdrawn from consideration but not cancelled: none
3. Claims pending: Claims 2 and 4-27
4. Claims allowed: none
5. Claims rejected: Claims 2 and 4-27

C. Claims on Appeal.

The claims on appeal are: Claims 2 and 4-27

IV. STATUS OF AMENDMENTS

The status of amendments filed subsequent to the final rejection are as follows:

No amendments after final rejection have been filed.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention is drawn to a computerized method which allows

•Prospective participants to identify clinical trials in which to participate,

•Selection of appropriate participants by personnel running clinical trials,

•AND Participation in the clinical trials by participants after they have been selected by

•Providing the participants with a clinical trial module

•Receiving data observations from the participants

•Storing the data observations

•Developing reports based on selected data observations

As explained on page 7, line 8 et seq., the system allows data to be obtained from remotely located data sources in a managed fashion, and allows for the data to be analyzed and used for a clinical trial. In the context of a clinical trial, participants can be recruited through the Internet, and, after they are accepted as participants, data can be collected remotely through the Internet for use in a clinical trial.

A concise explanation of independent claims 2, 14, and 26 is presented in the following tables which identify portions of the application (e.g., Figures and numeric identifiers; page and line numbers) pertaining to the claimed subject matter (it being understood that these are not the only portions of the application which describe features of the claimed invention).

2. A clinical trial data management server method, comprising:	Figure 2 shows a system for clinical trial data management. Item 215 identifies clinical trials recruitment. Item 330 pertains to a medical device associated with a clinical trial data management client 210. Item 240 shows storage of clinical trials data. Figure 4 shows a flow chart for recruitment of participants in clinical trials. See also Figure 7 which shows the preferred recruitment routine. Figure 5 shows a flow chart for receiving data from a client and managing the trial after recruitment. See also Figure 8 for data management routines. Page 17, line 15 explains that the data engine 100 (Figure 2) is preferably implemented on a secure server.
receiving, at a server, a user profile provided by a client;	Figure 7 shows receiving a user profile from a client at step 1210. Page 15, line 3 et seq. describes receiving the user profile. Figure 2 shows that personal information data received from prospective clients can be stored in database 220.

based on said user profile, indicating to said client one or more matching clinical trials;	Step 1220 in Figure 7 shows identifying clinical trial matches that fit the user profile. A user could qualify to participate in more than one clinical trial at the same time. Page 15, lines 12 et seq., discusses matching of clinical trials according to the profile sent by the recruitment client 215 (Figure 2).
receiving a clinical trail selection from said client;	Steps 1230 and 1250 in Figure 7 show that the client is provided with a listing of trials from which the client makes a selection on which trials to participate in. Page 15, line 21 et seq. Discusses determining if a clinical trial selection by a prospective participant has been made.
providing to said client a selected clinical trial module, indicated by said clinical trial selection and corresponding to a selected one of said matching clinical trials, said module being adapted to obtain clinical trial data including a respective data observation;	Step 1260 in Figure 7 shows sending a clinical trial module to the client. Figure 2 shows the clinical trials module 290 comes from the data engine 100 (the server-see page 17 at line 15). As explained on page 16, lines 8 et seq., the clinical trials module will allow the approved participant to participate in the selected clinical trial.

receiving, at said server, said respective data observation;	Figure 2 shows information being provided from the clinical trial data management client (i.e., a client that has been accepted into the trial and is participating in the trial) to the data engine 100. Figure 8 shows a flow chart for data management. Step 1410 pertains to determining if data has been received from the client. Page 16, lines 15 et seq. discusses receiving data from the clinical trials data management client 210 (Figure 2) using the processes of Figure 8. Page 11 lines 9 et seq. explains that the data can be provided by the client 210 or can be obtained from a device 330 that communicates with the client (see also step 401 in Figure 11, and the discussion on pages 24 and 25 of the application beginning on page 24 at line 21).
storing said respective data observation in a database of data observations; and	Figure 2 shows storage of clinical trials data at 240. Step 1430 in Figure 8 shows storage of the data in a database. Page 16, line 27 et seq. discusses storage of the data obtained from the client.

in response to a report request: retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of observations; and producing a report based on said plurality of retrieved observations.	Steps 1440, 1450 and 1460 in Figure 8 shows receiving report requests, generating reports, and sending reports. Page 17, lines 3-12 shows describes the process steps 1440, 1450 and 146 depicted in Figure 8.

14. A clinical trial data server, comprising:	Figure 2 shows a system for clinical trial data management. Item 215 identifies clinical trials recruitment. Item 330 pertains to a medical device associated with a clinical trial data management client 210. Item 240 shows storage of clinical trials data. Page 17, line 15 explains that the data engine 100 (Figure 2) is preferably implemented on a secure server.

a data engine receiving a user profile provided by a client;	Data engine 100 is shown in Figure 2. Prospective client 215 provides a user profile to the data engine. Step 620 in Figure 4 shows sending the user profile to the data engine. Page 12, lines 26 et seq. discuss sending the user profile. See also Figure 7 which shows receiving a user profile from a client at step 1210. Page 15, line 3 et seq. describes receiving the user profile.
clinical trials management module for analyzing said user profile and indicating to said client one or more matching clinical trials;	Figure 2 shows the clinical trials management module 290. Communication with the prospective participant 215 occurs at 260. Step 630 in Figure 4 shows sending a list of matching trials to the prospective client based on the profile. See also Step 1220 in Figure 7 which shows identifying clinical trial matches that fit the user profile. A user could qualify to participate in more than one clinical trial at the same time. Page 15, lines 12 et seq., discusses matching of clinical trials according to the profile sent by the recruitment client 215 (Figure 2).

one or more clinical trial modules adapted to obtain clinical trial data, including respective data observations;	Page 16, lines 8 et seq., indicates the clinical trials module will allow the approved participant to participate in the selected clinical trial. Figure 2 shows that after a person is accepted into a clinical trial, he becomes a clinical trial data management client 210 and can send measurements he makes or which are made by a device 330.
said clinical trials management module providing to said client a selected one of said one or more clinical trial modules, indicated by a clinical trial selection, and corresponding to a selected one of said matching clinical trials.	Step 1260 in Figure 7 shows sending a clinical trial module to the client which pertains to a plurality of modules that are available which the client can select from a list (step 1230).

26. A clinical trial client for use on a computer, comprising:	Figure 2 shows clients 215 and 210. Until recruited, the client is a prospective participant in one or more trials and is referred to as a recruitment client 215. After the prospective client identifies trials he wants to participate in, and is accepted for those trials, he is provided with a clinical trials management module for that trial and becomes a client trial data management client 210. Page 10, lines 23 et seq. discuss the clinical trials data management client 210 and recruitment client 215.
a module for sending user profile to a clinical trial data server;	Step 620 in Figure 4 shows sending the user profile to the data engine. Page 17, line 15 explains that the data engine 100 (Figure 2) is preferably implemented on a secure server. See also Figure 7 which shows receiving a user profile from a client at step 1210. Page 15, line 3 et seq. describes receiving the user profile.
a module for receiving from said clinical trial data server an indication of one or more matching clinical trials;	Step 630 in Figure 4 shows receiving a listing of clinical trials which match the user profile.

a module for accepting a user selection of one of said one or matching clinical trials, and sending to said clinical trial data server a clinical trial solution; and	Step 640 in Figure 4 shows that the client module sends an acceptance of one or more trials based on the list of matching trials.
a module for receiving and installing a selected clinical trial module corresponding to said clinical trial selection, the selected clinical trial module being adapted to obtain clinical trial data, including a respective data observation, from a clinical trial subject.	Page 16, lines 8 et seq., indicates the clinical trials module will allow the approved participant to participate in the selected clinical trial. Figure 2 shows that after a person is accepted into a clinical trial, he becomes a clinical trial data management client 210 and can send measurements he makes or which are made by a device 330.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The sole ground of rejection to be reviewed on appeal is the rejection of claims 2 and 4-27 as being anticipated under 35 U.S.C. 102(e) over U.S. Patent Publication 2001/0051882 to Murphy.

ARGUMENT VIIA. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

There are no rejections under 35 U.S.C. §112, first paragraph.

ARGUMENT VIIB. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

There are no rejections under 35 U.S.C. §112, second paragraph.

ARGUMENT VIIC. REJECTIONS UNDER 35 U.S.C. §102

Claims 2 and 4-27 were rejected as being anticipated by U.S. Patent Publication to Murphy. This rejection is in error, as Murphy merely shows a system for matching clinical trial to qualified participants (See the Abstract and face page showing matching system 110).

Clinical trials can be lengthy processes involving many subjects and many many observations. In the present application, the inventors have devised a method which allows people to be (1) recruited and (2) participate in a clinical trial in a secure and expeditious manner. Prior to the invention by the applicants, having rolling participation in clinical trials was more difficult and labor intensive. The invention allows people to be recruited and then to provide data that is used in the trial on a rolling basis where entry of the participant, and receipt and handling of the data is performed by a computerized system which is secure and involves significantly less management effort than prior methods. Murphy does not perform this function. Rather, Murphy only describes a system for allowing a person to be matched to trials in which he or she qualifies. At no point does Murphy show, describe or suggest providing a clinical trial data management module which allows the user to participate in the trial by providing data to the trial manager.

As discussed in detail above, Figure 2 of the patent application depicts a clinical trial data management client 210 differently from a clinical trials recruitment client 215. With respect to the recruitment client 215, the prospective trial participant provides a user profile and receives a listing of trials which match his profile. This is somewhat akin to the matching system of Murphy (although Murphy operates by different procedures). However, the claimed invention is much more than a matching system. The claimed invention is able to address the complex management problem of rolling admissions to clinical trials that are in progress. Unlike Murphy, the invention requires that the client, after the client selects a trial or trials in which he desires to participate and is approved for participation (see 1250 in Figure 7), be provided with a clinical trials module (see 1260 in Figure 7). With reference to

Figure 2 of the application, the now accepted client (referred to as "clinical trial data management client 210"), participates in a trial by providing observation data (manually input or provided by a device 330) through communication link 260b.

With reference to page 4 of the office action mailed April 17, 2007, it can be seen that the Examiner has erroneously concluded that paragraphs [0024] and [0034] of Murphy show provisioning of a client with a module adapted to obtain clinical trial data and receiving clinical trial data. However, at no point in either paragraph in Murphy is actual clinical trial data from a participant in a trial provided from the client to a server. As explained in paragraph [0024] of Murphy "The initial assessment 320 is comprised of a short questionnaire that is intended to gather information that will immediately narrow the list of trials for which the user may be a potential candidate" (emphasis mine). In short, NO DATA FOR A TRIAL is being provided by module 320. Module 320 simply is NOT adapted to obtain clinical trial data including a respective data observation as required in claims 2, 14 and 26.

With reference to Figure 5 of Murphy, the first words on the screen are **Initial Assessment Questionaire**. With reference to paragraph [0024] of Murphy it is clear that Murphy has a system for matching prospective participants to clinical trials in which they may participate, but Murphy does not show or contemplate an integrated system whereby prospective participants can review trials in which they might participate (through matching of information in a way which could be similar to or different from that shown in Murphy), apply to participate (and be rejected or accepted), and, if accepted, be provided with a module which is adapted to obtain clinical trial data. Note that in the practice of the invention, not everybody that has an interest in a clinical trial would get the clinical trial module. Some of them would not fit the criteria needed for the trial, a clinical trial might be closed after it receives all the desired participants, etc. The invention allows selection of participants, provisioning a module to participants for obtaining data, receiving data from participants, and being able to generate clinical trial reports and analysis based on the data. Murphy wholly lacks this integrated system concept and merely provides a

matching process and system.

Paragraph [0034] of Murphy does not make up for the deficiencies of Paragraph [0024]. As noted in Paragraph [0034], the system described in Murphy is a **matching system** which can be used on the Internet. Paragraph [0034] indicates that the matching system provides a "pool of individuals against which the criteria for specific trials can be compared, to identify possible candidates". Thus, this paragraph also does not show or suggest transfering a clinical module to a client which allows participating in a trial, or the client using the clinical trial module to send in observations pertinent to the clinical trial

On page 3 of the office action of April 17, 2007, the Examiner states:

"Furthermore, Murphy discloses the initial questionnaire is comprised of more detailed questions than those asked in the initial assessment 320. Specifically, the questionnaire may ask questions concerned **with the medical history** (see section 0026) in contrast with applicant's assertion no data respective data information of any kind is provided in Murphy" (emphasis original)

However, claim 2 requires

providing to said client a selected clinical trial module, indicated by said clinical trial selection and corresponding to a selected one of said matching clinical trials, said module being adapted to obtain clinical trial data including a respective data observation;

receiving, at said server, said respective data observation.

As can be plainly seen, answering medical history questions to a trial that a participant has not already been accepted or agreed to participate is not clinical trial data. Further, it is not a respective data observation that relates to a clinical trial. Rather, within the plain language of Murphy, these answers to questions are used to help select a person for participation in a trial, and they are not data that is being used in a trial.

Similarly, claim 14 requires:

one or more clinical trial modules adapted to obtain clinical trial data,

including respective data observations;

Also, similarly claim 26 requires:

a module for receiving and installing a selected clinical trial module corresponding to said clinical trial selection, the selected clinical trial module being adapted to obtain clinical trial data, including a respective data observation, from a clinical trial subject.

For at least the above reasons the rejection should be reversed.

Argument VIID. REJECTIONS UNDER 35 U.S.C. §103

There are no rejections under 35 U.S.C. §103.

ARGUMENT VIIE. REJECTION OTHER THAN 35 U.S.C. §§102, 103 AND 112

There are no rejections other than the rejection under 35 U.S.C. §102, discussed above.

VIII. CLAIMS APPENDIX

The text of the claims involved in the appeal are:

2. A clinical trial data management server method, comprising:

receiving, at a server, a user profile provided by a client;

based on said user profile, indicating to said client one or more matching clinical trials;

receiving a clinical trail selection from said client;

providing to said client a selected clinical trial module, indicated by said clinical trial selection and corresponding to a selected one of said matching clinical trials, said module being adapted to obtain clinical trial data including a respective data observation;

receiving, at said server, said respective data observation;

storing said respective data observation in a database of data observations; and

in response to a report request:

retrieving selected ones of said data observations from said database in accordance with parameters in said report request to provide a plurality of observations; and

producing a report based on said plurality of retrieved observations.

4. The clinical trial data management server method as set forth in claim 2, wherein said clinical trial data is provided to said server by a data sampling device.

5. The clinical trial data management server method as set forth in claim 2, wherein said clinical trial data is provided to said server over the Internet.

6. The clinical trial data management server method as set forth in claim 2, wherein said clinical trial data is provided to said server by a general-purpose computing device having said clinical trial data manually inputted by a user.

7. The clinical trial data management server method as set forth in claim 6, wherein said general-purpose computing device is one of: a personal computer, a handheld computing device, and a telephone.

8. The clinical trial data management server method as set forth in claim 2, wherein:

said server includes a data engine;

said server comprises a plurality of modules, including said selected clinical trial module, a health data management module, and a clinical trials management module;

said health data management module comprises data analysis algorithms used by said data engine to analyze said clinical trial data; and

said clinical trials management module:

selects said one or more matching clinical trials, based on said user profile;

provides an approval of said clinical trial selection; and

provides said selected clinical trial module.

9. The clinical trial data management server method as set forth in claim 8, wherein said clinical trials management module performs said selecting of said one or more matching clinical trial by comparing said received user profile with clinical trial profiles stored in a clinical trials database.

10. The clinical trial data management server method as set forth in claim 8, wherein said health data management module comprises data analysis algorithms and is adapted to accept data for one or more of: cardiology data, diabetes data, allergy data, and immunology data.

11. The clinical trial data management server method as set forth in claim 8, wherein said health data management module is adapted to send analyzed data to said client, said analyzed data comprising one or more of: a data display, complex data charting,

and trend identification.

12. The clinical trial data management server method as set forth in claim 11, wherein said complex data charting comprises mathematical EKG pattern analysis.

13. The clinical trial data management server method as set forth in claim 11, wherein said trend identification is based on a plurality of said data observations form a plurality of different medical devices.

14. A clinical trial data server, comprising:

a data engine receiving a user profile provided by a client;

clinical trials management module for analyzing said user profile and indicating to said client one or more matching clinical trials;

one or more clinical trial modules adapted to obtain clinical trial data, including respective data observations;

said clinical trials management module providing to said client a selected one of said one or more clinical trial modules, indicated by a clinical trial selection, and corresponding to a selected one of said matching clinical trials.

15. The clinical trial data server as set forth in claim 14, further comprising a health data management module receiving said respective data observations and said data engine storing said respective data observations in a database of data observations.

16. The clinical trial data server as set forth in claim 15, wherein said data engine is adapted to receive said clinical trail data from a data sampling device.

17. The clinical trial data server as set forth in claim 15, wherein said respective data observations are received over the Internet.

18. The clinical trial data server as set forth in claim 15, wherein said respective data observations are received from a general-purpose computing device.

19. The clinical trial data server as set forth in claim 18, wherein said general-purpose computing device is one of: a personal computer, a handheld computing device, and a telephone.

20. The clinical trial data server as set forth in claim 15, wherein:

said health data management module comprises data analysis algorithms used by said data engine to analyze said clinical trial data; and

said clinical trials management module:

selects said one or more matching clinical trials, based on said user profile;

provides an approval of said clinical trial selection; and

provides said selected clinical trial module.

21. The clinical trial data server as set forth in claim 20, wherein said clinical trials management module performs said selecting of said one or more matching clinical trial by comparing said received user profile with clinical trial profiles stored in a clinical trials database.

22. The clinical trial data server as set forth in claim 20, wherein said health data management module comprises data analysis algorithms and is adapted to accept data for one or more of: cardiology data, diabetes data, allergy data, and immunology data.

23. The clinical trial data server as set forth in claim 20, wherein said health data management module is adapted to send analyzed data to said client, said analyzed data comprising one or more of: a data display, complex data charting, and trend identification.

24. The clinical trial data server as set forth in claim 23, wherein said complex data charting comprises mathematical EKG pattern analysis.

25. The clinical trial data server as set forth in claim 23, wherein said trend identification is based on a plurality of said data observations form a plurality of different medical devices.

26. A clinical trial client for use on a computer, comprising:

a module for sending user profile to a clinical trial data server;

a module for receiving from said clinical trial data server an indication of one or more matching clinical trials;

a module for accepting a user selection of one of said one or matching clinical trials, and sending to said clinical trial data server a clinical trial solution; and

a module for receiving and installing a selected clinical trial module corresponding to said clinical trial selection, the selected clinical trial module being adapted to obtain clinical trial data, including a respective data observation, from a clinical trial subject.

27. The clinical trial client as set forth in claim 26, further comprising a module for sending said clinical trial data to said clinical trial data server.

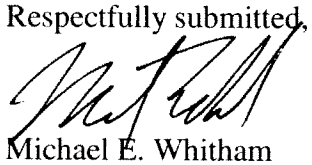
IX. EVIDENCE APPENDIX

There is no additional evidence on which Applicants rely in this Appeal.

X. RELATED PROCEEDINGS APPENDIX

There are no related proceedings involving this application.

Respectfully submitted,



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